MAY 27 2004

SECTION 9

510(k) SUMMARY K032397

This 510(k) summary of safety and effectiveness for Norseld Dual Yellow D10B laser is submitted in accordance with the requirements of SMDA 1990 and follows Office of Device Evaluation guidance concerning the organization and content of a 510(k) summary.

Applicant: Norseld Pty., Ltd.

Address: 9 Claxton St
Adelaide
South Australia 5000

Manufacturer: Norseld Pty, Ltd.
9 Claxton St
Adelaide
South Australia 5000

Contact Person: Mr. Peter Davis
Managing Director

Telephone Number: 011-8-8231 9000
Fax Number: 011-8-8231 9009

Preparation Date: January 2004
(of the Summary)

Device Name: Dual Yellow Laser, Dual Yellow D10B Laser

Common Name: Laser surgical device

Classification: Laser surgical device
Class II medical device
21 CFR 878.4810

Product Code: GEX
Panel: 79

Predicate devices: ICN (and SLS BIOPHILE) NLite Laser Systems (K000811, K020729, K013461, K014130); Candela Vbeam (K021180), and Norseld Dual Yellow Laser (K023899); Asclepion-Meditec YelloStar(K013940); COSMOS COMPACT KTP (K983020); Dio-Light/DioLite (K981447, K980201, K964074); Laserscope Lyra (K990903); and Viridis Laser (K001784).

Device description: The Norseld Dual Yellow D10B Laser is a copper bromide laser which emits it energy at 511 and 578 nm. The device consists of an cabinet, fiber optic delivery system, and a user/software interface.

Indications: The Dual Yellow laser is indicated for the treatment of benign pigmented and cutaneous vascular lesions.

The Dual Yellow laser, operating at 578 nm, is indicated in dermatology, plastic surgery, and general surgery for treatment of benign cutaneous vascular lesions including but not limited to:

Treatment of wrinkles,
Periocular wrinkles,
Periorbital wrinkles.
Facial and leg telangiectasia,
Rosacea,
Cherry angiomas,
Port wine stains,
Hemangiomas and venous lakes,
Angioma,
Spider angioma, and
Poikiloderma of Civatte,
Inflammatory Acne Vulgaris,
Verrucae/Warts,
Scars,
Striea, and
Psoriasis.

Podiatry - for benign cutaneous lesions and warts.

The Dual Yellow lase, operating at 511 nm, is indicated in dermatology, plastic surgery, and general surgery for treatment of benign cutaneous pigmented lesions including but not limited to:

Lentigines,
Solar keratoses,
Adenoma serabaceum,
Skin tabs,
Trichoepitheliomas (benign lesions similar to skin tags)
Naevi,
Keratoses,
Syringomas
Seborrhocic keratoses
Verrucae vulgaris, and
Warts.

Performance Data: Supporting literature and articles were provided in support of the indications for use of the 511 nm wavelength.

The results of a published clinical study were submitted in support of the indication for the treatment of inflammatory acne vulgaris using the 578 nm wavelength. Indications for the 578 nm wavelength were based on equivalency to cited legally marketed products.

CONCLUSION: Based on the information in the notification Norseld Pty., Ltd. believes that Dual Yellow D10B Laser is substantially equivalent to the cited legally marketed predicates for the indications listed above..

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 27 2004

Norseld Pty., Ltd.
c/o Mr. Roger Barnes
342 Sunset Bay Road
Hot Springs, Arkansas 71913

Re: K032397
Trade/Device Name: Norseld Pty., Ltd.
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: February 24, 2004
Received: March 1, 2004

Dear Mr. Barnes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SECTION 7

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K032397

Device Name: Norseld Pty., Ltd. Dual Yellow (Dual Yellow D10B Laser)

Indications for Use Statement:

The Dual Yellow laser, operating at 578 nm, is indicated in dermatology, plastic surgery, and general surgery for treatment of benign cutaneous vascular lesions including but not limited to:

Treatment of wrinkles,
Periocular wrinkles,
Periorbital wrinkles.
Facial and leg telangiectasia,
Rosacea,
Cherry angiomas,
Port wine stains,
Hemangiomas and venous lakes,
Angioma,
Spider angioma, and
Poikiloderma of Civatte,
Inflammatory Acne Vulgaris,
Verrucae/Warts,
Scars,
Striea, and
Psoriasis.

Podiatry - for benign cutaneous lesions and warts.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

Prescription Use X
(Per 21 CFR 801.109)

OR ~~Over-~~The Counter Use ___

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K032397

INDICATIONS FOR USE (continued):

The Dual Yellow lase, operating at 511 nm, is indicated in dermatology, plastic surgery, and general surgery for treatment of benign cutaneous pigmented lesions including but not limited to:

Lentigines,
Solar keratoses,
Adenoma serabaceum,
Skin tabs,
Trichoepitheliomas (benign lesions similar to skin tags)
Naevi,
Keratoses,
Syringomas
Seborrhoeic keratoses
Verrucae vulgaris, and
Warts.

Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K032397